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10/535,617	02/06/2006	Franco Bartoli	GK-ZEI-3279/500343.20300	7497

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EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT	PAPER NUMBER
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3769

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12/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,617	Applicant(s) BARTOLI, FRANCO	
	Examiner JEFFREY B. LIPITZ	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20,22-25,27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,22-25,27 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's drawing amendments filed October 6, 2009 are acknowledged but they do not overcome the drawing objection. Figures 2 and 11 contain numbers that are faded and spots throughout drawing and table. Please submit tables and drawings free of unwanted markings. Figures 13a and 13b have unlabeled axes and also contain unwanted spots. These spots are particularly confusing because most contain dots indicative of plots. Figures 14-17 have no elements labeled and contain elements that are barely discernable. For instance, the image of the person in Figures 14-16 has no outline and blends in with the background. Figure 18 contains a misspelling of the word "defects" in box 20.

Applicant's arguments/amendments filed October 6, 2009 with respect to the claim objections has been fully considered and is persuasive. The claim objections have been withdrawn.

Applicant's arguments/amendments with respect to the omission of steps/elements, antecedent basis, definitions of "defect" and "Zernike coefficients" and treating presbyopia rejected under 112 Second Paragraph have been fully considered and are persuasive. Therefore, the 112 rejections of claims 18, 20, 22-25, 27 and 30-31 have been withdrawn.

Applicant's argument with respect to the 112 Second Paragraph rejection of claim 31 has been fully considered but is not persuasive. It is unclear why a second control means would be necessary to control the same laser unit. Applicant asserts that

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this product claim is a corollary to method claim 24. However, one control unit can perform more than one step of controlling. Applicant's argument is not sufficient to explain the purpose of a second control means. The 112 Second Paragraph rejection of claim 31 is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 27 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 18, there are conditional steps recited which result in the same outcome – inducing a positive spherical aberration. The conditional steps of increasing the negative spherical aberration to obtain an overcorrect photoablative pattern OR changing the sign of a positive spherical aberration and then increasing it to obtain an overcorrect photoablative pattern are calculations that must be performed but do NOT constitute manipulative steps of the method. A manipulative step should be tied to a device or element or transform underlying subject matter, as interpreted under USC 101. The conditional steps are immaterial since one of ordinary skill in the art would only need to “obtain an overcorrect photoablative pattern inducing positive spherical aberration”. In other words, the conditional steps appear to be superfluous to the method, and it is thus unclear how they further modify the method.

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Regarding claims 20 and 27, it is unclear how these limitations further limit the scope of the invention. Applicant only teaches inducing a positive spherical aberration in the disclosure. Therefore, it appears that the method and apparatus of the present invention requires induction of this type of aberration. How else can the method reduce presbyopia? These limitations appear to be descriptive of the type of aberration induced to reduce presbyopia rather than identification of an additional step or element required for doing so. In addition claim 27 is unclear because it depends from itself.

Regarding claims 25, 27 and 29-31, Applicant's product claims are directed to a laser unit for performing cornea ablation comprising a control means. These claims are unclear for two reasons. First, a laser is not positively recited that can perform cornea ablation. Second, the control means includes an aberrometric measuring means, first and second pattern generating means and a supply means. These "elements" of the control means are not structural elements but rather functional limitations. All laser control means for corneal ablation are *capable* of measuring topography of the eye, generating patterns and supplying those patterns to the laser for implementation. Why is Applicant's *structure* unique? How do these functional limitations *necessarily* impose structural limitations on the control means? For the purposes of examination, Examiner has interpreted the laser unit to inherently include a laser and a control means. Furthermore, claims 27, 29 and 30 contain no additional elements or modifications to existing elements. Therefore, it is unclear how these claims further limit the scope of the claimed invention.

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Regarding claim 31, it is unclear why there is a second means for control, as discussed further in the Response to Arguments section, *supra*.

Applicant's arguments with respect to the apparatuses prior art rejections have been considered but are moot in view of the new grounds of rejection.

Applicant's arguments with respect to the methods prior art rejections have been considered but are not persuasive. Applicant asserts that Williams does not teach or suggest that a fourth order aberration should be induced. Although it is true that Williams does not describe his corrective approach in terms of inducing aberrations, nonetheless, the correction of a fourth-order aberration requires the induction of at least an equal (in absolute value) and opposite one. A negative spherical aberration for instance results in peripheral rays focusing closer to the lens than paraxial rays. Therefore, it is necessary to increase the power of the lens at the peripheral surfaces. The reshaping of the peripheral portions of the lens to increase its power is inherently a fourth order positive aberration. How else could the peripheral rays focus further away from the lens, or where the paraxial rays focus?

Therefore, the rejections of the method claims are maintained. The same rationale applies to the product claims, but a reference with more explicit details was found that was applied in this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 27, 29, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bille et al. (US Patent 6155684), hereinafter Bille.

Regarding claims 25, 27, 29 and 30, Bille teaches a control system for controlling an excimer laser, where the control unit uses a direct template of the target surface shape of the cornea to be obtained to control the amount of ablation to be accomplished in particular area (Column 5, Lines 38-52). The adaptive optical closed-loop system is used to measure the spatially modified profile prior to the surgery, during and after it. Bille teaches providing an adaptive system specifically in order to measure higher order aberrations (Column 4, Lines 5-23). As an example, Figure 5 is a plot measuring spherical aberration as a function of focus. Examiner interprets the system as capable and moreover intended to treat astigmatic disorders, which includes presbyopia (Background of the Invention). The second control means can include an additional

Regarding claims 25 and 28, a "first control means for controlling laser", a "generating means" and "means for acquiring" are recited, which are all interpreted as invoking 35 U.S.C. 112, sixth paragraph as they include functional language and do not include sufficient structure for achieving the specified function.

Bille teaches linking his diagnostic system to a laser control system (Column 5, Lines 38-50), his diagnostic system including a computer (22), which controls and records measurements of the second (myopia and hyperopia; Column 10, Lines 20-40) and fourth order (aberration) defects. These measurements are then used to generate a photoablative pattern. Examiner also directs Applicant's attention to the 112 2nd

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Paragraph rejections. These means for statements do not actually constitute new elements. A control system *capable* of transmitting ablative data and patterns to the laser is sufficient to accomplish these functions. The remaining limitations appear to be functional limitations that do not further modify the *structure* of the control system. These limitations receive negligible patentable weight.

Regarding claim 31, a "second means for controlling the excimer laser unit" is recited and interpreted as invoking 35 U.S.C. 112, sixth paragraph as it includes functional language and does not include sufficient structure for achieving the specified function. Bille teaches that a computer can use the acquire template or profile to control the amount of ablation (Column 5, Lines 43-45), thus suggesting a second control means or a second computer that directly controls the laser.

Claims 18, 20, 22-24 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (US 6,394,999 B1).

Regarding claims 18, 20, 22, 24 and 32-34, Williams teaches laser ablation (controlling a laser) or reshaping of the eye (specific photoablative treatment) that considers higher order aberrations of the eye (Column 3, Lines 41 and 42) and by expanding mathematical equations for refraction correction to include higher order effects, coma (3rd order) and spherical (4th order) aberrations can be reduced (Column 3, Lines 8-11). Williams teaches using wavefront sensing to provide an overall refractive analysis of the eye (acquiring an aberrometric map), e.g., taking into account the cornea, the lens, the vitreous and the retina (Column 4, Lines 20-22). When treating myopia (negative spherical aberration), the excimer laser is used to remove or ablate

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tissue from the cornea in order to flatten its shape (induce positive spherical aberration) (column 1, lines 24-26). The examiner interprets the claims as written in a conditional format, therefore only one "if" condition for each claim needs to be met. When a negative asphericity of the normal cornea contributes to a negative aberration content, the negative aberration is compensated for by a positive aberration contribution (inducement) from the gradient index nature of the lens (Column 3, Lines 20-22) and the excimer laser is used to remove or ablate tissue from the cornea in order to flatten its shape, wherein a positive spherical inducement in the in the 4th order inherently associated to presbyopia treatment. It should be noted that Bille could have been used to reject the method claims in substantially the same manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 6,394,999 B1) as applied to claims 18 & 25 in view of [C. E. Martinez et al., "Changes in corneal aberration structure after photorefractive keratectomy."

Regarding claim 23, William does NOT teach ablation with a customized ablative pattern to obtain even greater spherical aberration with a coefficient of Zernike's polynomial Z₄⁰.

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However, Martinez et al. teaches that spherical aberration is highly correlated with best spherical-correlated visual acuity in normal eyes and results show for 4th order aberration postoperative surgery, the Zernike coefficient for 60 patients with 7-mm pupil diameters equals 0.9999 (Table 5; par. 9, lines 3 & 4) and fourth-order Zernike coefficients Z11 through Z15 are indicators of spherical-like aberration. When values were calculated for a 3-mm pupil (Table 3), Z₁, Z₂, and Z₄ had changed by 1 month after surgery and never returned to preoperative values. In the 7-mm pupil calculations (Table 4), coefficients Z₁ and Z₄ had changed by 1 month after surgery (P.001) (par. 27 [Zernike Coefficients]), wherein patient's eyes are observed in location with dim lighting, causing the pupil to dilate.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the positive spherical aberration of William et al. by modifying the Zernike coefficient to equal 0.999 as taught by Martinez, therefore reducing the effects of presbyopia in the 4th order. The examiner interprets the claims as written in a conditional format, therefore only one 'if' condition for each claim needs to be met.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Magnante (6086204) teaches methods and devices for designing surfaces of corneal tissue that corrects the eye's optical aberrations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is

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(571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

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